298. Defendant Michael Arthur Traver is an urologist, licensed to practice medicine in Michigan, and, at all times relevant to the allegations of the complaint, one of the owners of Defendant GML. This defendant is a resident of the state of Michigan.

299. Defendant Kirit K. Vora is an urologist, licensed to practice medicine in Michigan, and, at all times relevant to the allegations of the complaint, one of the owners of Defendant GML. This defendant is a resident of the state of Michigan.

300. Defendant Jeffrey L. Weingarten is an urologist, licensed to practice medicine in Michigan, and, at all times relevant to the allegations of the complaint, one of the owners of Defendant GML. This defendant is a resident of the state of Michigan.

301. Defendant Bradley L. Willoughby is an urologist, licensed to practice medicine in Michigan, and, at all times relevant to the allegations of the complaint, one of the owners of Defendant GML. This defendant is a resident of the state of Michigan.

302. Defendant Raymond J. Winfield, Jr. is an urologist, licensed to practice medicine in Michigan, and, at all times relevant to the allegations of the complaint, one of the owners of Defendant GML. This defendant is a resident of the state of Michigan.

303. Defendant Phillip G. Wise is an urologist, licensed to practice medicine in Michigan, and, at all times relevant to the allegations of the complaint, one of the owners of Defendant GML. This defendant is a resident of the state of Michigan.

304. The Defendant GML Host Hospitals are the hospitals and ASCs identified in paragraphs 308 through 318 and any John Doe Defendants which are hospitals or ASCs under contract to GML for the provision of lithotripsy services.

305. Defendant Borgess Medical Center is a Michigan nonprofit corporation with a registered office at 1521 Gull Road, Kalamazoo, MI 49048. Defendant Borgess Medical Center furnishes lithotripsy to patients under arrangements with GML.

306. Defendant Hackley Hospital is a Michigan nonprofit corporation with a registered office at 34605 W. 12 Mile Road, Farmington Hills, MI 48331. Defendant Hackley Hospital furnishes lithotripsy to patients under arrangements with GML.

307. Defendant Holland Community Hospital is a Michigan nonprofit corporation with a registered office at 602 Michigan Avenue, Holland, MI 49423. Defendant Holland Community Hospital furnishes lithotripsy to patients under arrangements with GML.

308. Defendant North Ottawa Community Hospital is a Michigan nonprofit corporation with a registered office at 1309 Sheldon Road, Grand Haven, MI 49417. Defendant North Ottawa Community Hospital furnishes lithotripsy to patients under arrangements with GML.

309. Defendant Port Huron Hospital is a Michigan nonprofit corporation with a registered office at 1221 Pine Grove Avenue, Port Huron, MI 48060. Defendant Port Huron Hospital furnishes lithotripsy to patients under arrangements with GML.

310. Defendant Providence Hospital and Medical Center, Inc. is a Michigan nonprofit corporation with a registered office at 28000 Dequindre, Warren, MI 48092. Defendant Providence Hospital and Medical Center, Inc. does business as Providence Hospital and Medical Center. Defendant Providence Hospital and Medical Center, Inc. furnishes lithotripsy to patients under arrangements with GML.

311. Defendant Spectrum Health Hospitals is a Michigan nonprofit corporation with a registered office at 100 Michigan Street, N.E., Mail Code 60, Grand Rapids, MI 49503. Defendant Spectrum Health Hospitals furnishes lithotripsy to patients under arrangements with GML.

312. Defendant Spectrum Health Kelsey dba Kelsey Memorial Health Center is a Michigan nonprofit corporation with a registered office at 100 Michigan Street, N.E., Mail Code 60, Grand Rapids, MI 49503. Defendant Spectrum Health Kelsey dba Kelsey Memorial Health Center furnishes lithotripsy to patients under arrangements with GML.

313. Defendant St. John River District Hospital is a Michigan nonprofit corporation with a registered office at 28000 Dequindre, Warren, MI 48092. Defendant St. John River District Hospital furnishes lithotripsy to patients under arrangements with GML.

314. Defendant Trinity Health-Michigan is a Michigan nonprofit corporation with a registered office at 34605 W. 12 Mile Road, Farmington Hills, MI 48331. Defendant Trinity Health-Michigan does business as Lakeshore Surgery Center and Mercy Hospital Port Huron. Defendant Trinity Health-Michigan furnishes lithotripsy to patients under arrangements with GML.

315. Defendant William Beaumont Hospital is a Michigan nonprofit corporation with a registered office at 3601 W. 13 Mile Road, Royal Oak, MI 48073. Defendant William Beaumont Hospital furnishes lithotripsy to patients under arrangements with GML.

316. HealthTronics is a publicly traded corporation, headquartered at 9825 Spectrum Drive, Austin, TX 78717.

317. The Defendant HealthTronics Urologists are those John Doe Defendant who are urologist owners of an UOL Partnership, which is controlled by HealthTronics. Controlled by means that either HealthTronics or a subsidiary or affiliate of HealthTronics owns an interest in the UOL Partnership or manages the UOL Partnership or otherwise has the power to direct the day-to-day operations of such UOL Partnership.

318. The Defendant HealthTronics UOL Partnerships are those John Doe UOL Partnerships controlled by Defendant HealthTronics.

319. The Defendant HealthTronics Hospital are those John Doe Host Hospitals under contract to a HealthTronics controlled UOL Partnership.

320. Defendant Lincolnland Lithotripsy, LLC is a Delaware limited liability company, authorized to conduct business in Illinois, headquartered at 14650 Cotton Hill Road, Pawnee, IL 62558, and with a registered office in Illinois at 233 S. Wacker Drive, #7800, Chicago, IL 60606.

321. Defendant United Shockwave Therapies, LLC is a Delaware limited liability company, headquartered in Illinois, and with a registered office at 1111 E. Touhy Ave #240, Des Plaines, IL 60016.

322. Defendant United Shockwave Services, Ltd. is an Illinois corporation having a registered office at 1111 E. Tuohy Ave #240, Des Plaines, IL 60016.

323. The Defendant United Shockwave are the John Doe Defendants that are UOL Partnerships controlled by or managed by United Shockwave Services or United Shockwave Therapies.

324. The Defendant United Shockwave Host Hospitals are the hospitals identified in Paragraphs 327 – 330 and those John Doe Defendants which are under contract to a United Shockwave UOL Partnership for the provision of lithotripsy services.

325. Defendant Advocate Heath and Hospitals Corporation is an Illinois not-for-profit corporation ("Advocate Heath") with a registered office at 2025 Windsor Drive, Oak Brook, Illinois 60523. Defendant Advocate Health contracted with an UOL Partnership controlled by or managed by United Shockwave Services or United Shockwave Therapies for the provisions of lithotripsy services.

326. Defendant Morris Hospital is an Illinois not-for-profit corporation ("Morris Hospital") with a registered office at 150 W. High Street, Morris, Illinois, 60450. Defendant

Morris Hospital contracted with an UOL Partnership controlled or managed by United Shockwave Services or United Shockwave Therapies for the provision of lithotripsy services.

327. Defendant Katherine Shaw Bethea Hospital is a not-for-profit Illinois corporation ("KSB Hospital") with a registered office at 100 E. First Street, Dixon, IL 61021. Defendant KSB Hospital contracted with Defendant United Shockwave, an UOL Partnership for the provision of lithotripsy services.

328. Defendant VHS Westlake Hospital, Inc. is a Delaware corporation ("Westlake Hospital") which is authorized to do business in Illinois and has a registered office in Illinois at 200 West Adams Street, Chicago, IL 60606. Defendant VHS Westlake Hospital does business as Westlake Hospital. Defendant VHS Westlake Hospital contracted with an UOL Partnership controlled by United Shockwave Services or United Shockwave Therapies for the provision of lithotripsy services.

329. Defendant Dr. Joel Slutsky is an urologist, licensed to practice in Illinois who owns an interest in an UOL Partnership controlled by United Shockwave Services or United Shockwave Therapies.

330. The Defendant John Doe UOL Partnerships those John Doe defendants which are UOL Partnerships controlled by a defendant that is a Syndicator or Management Company, as those terms have been defined herein. The phrase controlled by means that a Syndicator or Management Company or a subsidiary or affiliate of either of them owns an interest in such UOL Partnership, manages the UOL Partnership or otherwise has the power to direct the day-to-day operations of such UOL Partnership.

331. The Defendant John Doe Urologists are those John Doe defendants who are physicians who own an interest in an UOL Partnership.

332. The Defendant John Doe Host Hospitals are those John Doe defendants which are under contract with an UOL Partnership for the provision of lithotripsy services.

333. The Defendant John Doe Syndicators are those John Doe defendants who have organized one or more UOL Partnerships such as by arranging for a private offering of interests in such UOL Partnerships to urologists, actively recruiting such urologists, causing the UOL Partnership to be organized as a legal entity, participating, either directly or through a controlled subsidiary or affiliate, in the management of the UOL Partnership, and obtaining contracts with Host Hospitals for the UOL Partnership. Such Syndicators may directly or indirectly own an interest in such UOL Partnerships, act as a general partner of an UOL Partnership or a manager of an UOL Partnership.

334. The Defendant John Doe Management Companies are those John Doe defendants who manage the day-to-day operations of an UOL Partnership or control an UOL Partnership such as by acting as the manager of or the general partner of an UOL Partnership. Typically, these Management Companies are controlled by a Syndicator or is under common control with a Syndicator.

BACKGROUND ALLEGATIONS

335. Lithotripsy is a non-invasive procedure that uses shock waves to break up stones that form in the kidney, urethra and urinary bladder (collectively, "kidney stones"). Lithotripsy is also known as extracorporeal shock wave lithotripsy, often referred to by the initials "ECSWL" or "ESWL".

336. ESWL is a procedure in which shock waves, created outside the body, travel through the skin and body tissues until they hit the kidney stones. As a result, the kidney stones are broken down into sand-like particles and are more easily passed through the urinary tract.

337. Lithotripters, the machines that deliver the shockwaves used in lithotripsy, first became available in the United States in 1984. The initial lithotripters were very large and very expensive and were provided at a fixed site, usually a hospital.

338. Many states regulate lithotripsy by requiring a certificate of need ("CON") for lithotripsy services. In these states, a business must obtain a CON before it can purchase or rent lithotripsy equipment to a provider in that state who will use it to perform lithotripsy. Additionally, a CON is needed to expand the service area in which an existing provider is authorized to provide lithotripsy services.

339. A UOL Partnership can be the holder of a CON for lithotripsy and thus hospitals must contract with an UOL Partnership holding a CON in order to obtain the use of a lithotripter.

340. Eventually, compact lithotripters were developed that were much less expensive than the large lithotripters. By the mid-1990s, compact lithotripters were small enough to be easily transported from site to site in a large van or truck and easily set up within an operating room or treatment room in a hospital or other facility. The development of such transportable lithotripters and the approval of their use by the FDA in 1996 launched the mobile lithotripsy industry.

341. The term "lithotripsy equipment" refers to the lithotripter which generates the shockwaves, the control equipment which provides x-ray, fluoroscope or ultrasound guidance during the procedure, the table on which the patient lies, computer equipment and other related equipment. In short, it includes all the equipment used by a physician to perform lithotripsy.

342. In a mobile lithotripsy model, the lithotripter is driven in a van or truck from site to site on a rotating basis, usually staying at one site for a half-day or a day at a time.

343. Lithotripsy is performed in an operating room or a treatment room at a hospital or other facility. Generally, patients receive anesthesia administered by an anesthesiologist to

minimize the discomfort and pain of the procedure and to limit movement. Hospital staff, including nurses, prepare the patient for the procedure.

344. An urologist trained to perform lithotripsy typically conducts the procedure with the assistance of a trained technician who assists in positioning the patient and in operating the equipment.

345. Mobile lithotripsy is typically a "turn key" operation with lithotripsy companies providing all the equipment that is needed for the procedure and the skilled technician who operates the lithotripsy equipment during the procedure as directed by the urologist.

DESCRIPTION OF THE SCOPE OF THE FRAUD

346. Approximately one million ESWL lithotripsy procedures are performed in the United States each year.

347. Hospitals bill Medicare, Medicaid and other federal healthcare programs for the facility fee associated with the lithotripsy procedure. In 2010, the maximum allowed reimbursement rate for this facility fee under HOPPS is $2781.00. If all one million lithotripsy procedures were reimbursed by Medicare, the federal government would be paying **$2.781 billion** in facility fees for the performance of lithotripsy in hospitals. Based on estimates that thirty percent of the patients receiving ESWL lithotripsy are Medicare patients, Medicare, on an annual basis, is estimated to pay **$834 million** in facility fees for the performance of lithotripsy in hospitals.

348. In addition, the urologist performing the lithotripsy procedure (generally not an employee of the hospital) would bill separately for and be reimbursed separately for the professional component of the procedure.

349. In 2010, under the Medicare physician fee schedule, the maximum allowed reimbursement for a physician performing lithotripsy in a facility is $596.00. Based on one million

ESWL lithotripsy procedures per year, Medicare would be paying **$596 million** in professional fees to the urologists performing lithotripsy. Based on estimates that thirty percent of patients receiving ESWL lithotripsy are Medicare patients, Medicare, on an annual basis, is estimated to pay **$178.8 million** in professional fees to the urologists performing lithotripsy.

350. In addition, some lithotripsy services involve the delivery of anesthesia by an anesthesiologist. The fee for the professional services furnished by the anesthesiologist are typically billed separately to Medicare under the physician fee schedule.

351. In addition, diagnostic imaging tests (DHS under Stark) are performed prior to a lithotripsy procedure and weeks later as a follow-up to the procedure. Either an x-ray, ultrasound, fluoroscopy, CT scan, or intravenous pyelogram (all DHS) is given to the patient in order to diagnose whether a patient is a candidate for lithotripsy prior to scheduling a lithotripsy procedure. A CT scan or intravenous pyelogram (both DHS) are performed weeks after the lithotripsy procedure is performed to determine whether any portion of the stone remains.

352. Urologists owning an interest in an UOL Partnership make thousands of referrals to a hospital for inpatient and outpatient services. The services include laser procedures to treat benign prostate hyperplasia, prostatic cryotherapy, cryosurgery procedures to treat prostate, renal and liver cancers, radiation therapy (IMRT, IGRT) to treat prostate cancer, renal lithotripsy, urologic laser ablation, and prostatic brachytherapy.

353. The National Cancer Institute has determined the number of Medicare patients diagnosed with prostate cancer, kidney cancer or liver cancer each year from 1986 through 2005. In 2005, 17,436 cases of prostate cancer, 2,624 cases of kidney cancer and 1,097 cases of liver cancer were diagnosed in Medicare patients. Nationally, 217,000 new cases of prostate cancer are diagnosed each year.

354. In 2006, the national cost of treating newly diagnosed prostate cancer cases was $3.916 billion and for kidney cancer, $941 million. Continuing care for prostate cancer patients in 2006 alone was $5.028 billion dollars and for kidney cancer, $1.260 billion. The costs of treating just these two types of cancers total **$11.145 billion** per year.

355. Medicare bears a substantial portion of these costs. In 2009, Medicare fee-for-service payments for cancer care totaled $29 billion. $13.4 billion, 47% of this $29 billion, was paid for inpatient and outpatient hospital care. $12.2 billion, about 42% of the $29 billion, was paid to physicians as professional fees.

356. Prostate cancer accounted for 11% of the Medicare cancer expenditures in 2006. Based on the foregoing estimates, Medicare spends as much as $1.499 billion a year on inpatient and outpatient hospital services in treating prostate cancer ($29 billion x 11% x 47%).

357. Additionally, Medicare spends as much as $1.40 billion on physician fees to treat prostate cancer each year.

358. Urologists also earn significant professional fees in treating such patients.

359. Urologists control referrals for inpatient and outpatient services delivered to treat prostate, kidney or liver cancer patients.

360. Through their control over **$11.145 billion** to treat prostate cancer and kidney cancer patients, Urologists exert significant control over Host Hospitals.

361. The UOL Partnership receives remuneration as a per procedure fee from the hospitals under contract to it for the use of the lithotripsy equipment and the technician as well as remuneration in the form of the exclusive right to provide lithotripsy equipment to the hospital.

362. A urologist owner of an UOL receives remuneration in the following ways: (i) as a profit distribution from the UOL Partnership whose earnings are solely based upon the per

procedure fees it earns from its exclusive arrangement with hospitals and ASCs under contract to it; (ii) as a professional fee for the lithotripsy procedure personally performed by the urologist owner at one of the hospitals under contract to the UOL or as a salary from the hospital; and (iii) as professional fees for other urological inpatient services (DHS under Stark) and outpatient services (DHS under Stark) that the urologist owner performs at the hospital.

363. The hospital receives remuneration in the form of the facility fee for the lithotripsy procedures performed at the hospitals. The hospital also receives remuneration in the form of fees associated with the DHS referrals made by the urologist owners of the lithotripsy partnerships.

The Model of Physician Owned Lithotripsy Partnerships

364. Diagrams setting forth the components of this model and the relationship between each component are attached as Exhibit A and Exhibit B.

365. There is a lithotripsy company that organizes and controls the UOL Lithotripsy Partnerships ("UOL Partnership") and every other company involved in the provision of lithotripsy equipment and/or personnel to a hospital or ambulatory surgical center. This controlling company will be referred to as a "Syndicator" and is defined below.

366. The Syndicator is usually already in the lithotripsy business.

367. The Syndicator is frequently a distributor (or controls a distributor) of the lithotripsy equipment and thus either sells the lithotripsy equipment or leases it to the UOL Partnership which in turn has a contract with one or more hospitals, referred to as "Host Hospitals", pursuant to which each Host Hospital pays per procedure fees to use the lithotripsy equipment and a trained technician.

368. The Syndicator establishes an UOL Partnership targeted at hospitals within the geographic range of the proposed mobile lithotripsy services.

369. The partnership includes a company which manages the day-to-day operations of the UOL Partnership. This company will be referred to as a "Management Company."

370. The Management Company is typically owned by the Syndicator or is otherwise controlled by the Syndicator such as through common ownership or contractual control.

371. The Syndicator or its Management Company strategically recruits urologists to become the majority owners of the UOL Partnership. The urologist owners are referred to as the "Urologists" as defined below. Occasionally, anesthesiologists or hospitals are permitted to own minority interests in these UOL Partnerships.

372. One of the ways in which the Syndicators or Management Companies actively recruit urologists is by attending professional trade shows at which urologists are present. Urologists are encouraged to invest in a UOL Partnership and to convince the hospitals with which they have a relationship to switch lithotripsy services companies at the end of a contract period and to then contract with one of the Syndicators' or Management Companies' UOL Partnership for lithotripsy services.

373. The minority owners are usually the Syndicator or its Management Company and in some cases, some of the Host Hospitals or some of the anesthesiologists who deliver anesthesia during lithotripsy procedures.

374. The recruited Urologists must either be on staff at the targeted hospital or have a relationship with the targeted hospital.

375. The Urologists do not participate in the management of the UOL Partnership because the Management Company does everything necessary to deliver the lithotripsy equipment, personnel and conduct the day-to-day operations of the UOL Partnership.

376. The Syndicator and the Management Company know that these Urologists control referrals for services to the targeted hospital, including lithotripsy services.

377. Once established, the UOL Partnership pursues a contract with one or more hospitals or ambulatory service centers, referred to as "Host Hospitals" and defined below, pursuant to which each Host Hospital pays per procedure fees to use the lithotripsy equipment and a trained technician.

378. The contract between the UOL Partnership and the Host Hospital is an exclusive contract in that the Host Hospital agrees not to contract with any one else for the provision of lithotripsy equipment and related services.

379. The Host Hospitals know that the Urologists on staff at the hospital have an ownership interest in the UOL Partnership.

380. The Urologists leverage their referrals to the Host Hospital by insisting that the Host Hospital use the UOL Partnership in which they have an ownership interest for lithotripsy procedures and the Urologists tie their referrals to inpatient and outpatient services to the Host Hospital's lithotripsy contract. These DHS include laser treatments for benign prostate hypertrophy, cryosurgery or cryotherapy for prostate, renal, and liver cancers, and, radiation treatments, diagnostic imaging tests including ultrasounds used to diagnose a patient as being a candidate for lithotripsy.

381. Use of the UOL Partnership is a condition for referral of DHS by the Urologists.

382. Rates for the lithotripsy service extracted as a condition for referrals are far above true market rates, providing the urologists and the lithotripsy management company exorbitant income from the UOL Partnership.

383. Accordingly, the Syndicator, the Management Company, the UOL Partnership and its Urologist owners enter into a *quid pro quo* arrangement with the Host Hospitals. The Host Hospitals agree to contract with the UOL Partnership in exchange for the Urologists agreeing to continue making referrals to the Host Hospital for inpatient and outpatient urological services as well as for lithotripsy, which services are all payable by public health care programs.

The Role of the Syndicator

384. The Syndicator benefits from this arrangement by keeping competitors from contracting with the Host Hospitals or from undercutting the price charged by the Syndicator. The Syndicator's co-owners, the Urologists, benefit by deriving the profit from increasing the number of referrals for lithotripsy services made to UOL Partnerships.

385. The Syndicator, as a minority member of an UOL Partnership, receives profit distributions from the UOL Partnerships. Accordingly, the Syndicator shares in any kickbacks received by the UOL Partnerships in which it is a member.

386. The arrangement ensures a steady stream of business for the UOL Partnership, management fees for the Management Company, sales or rental fees for the Syndicator when it sells or rents the lithotripter to the UOL Partnership, and healthy profit distributions from the UOL Partnership to all of its owners, the majority of whom are urologists and the rest of whom include the Syndicator, the Management Company, or a Syndicator Affiliate.

The Role of the Management Company

387. The Management Company will typically have a contract with the UOL Partnership to provide management services to the UOL Partnership.

388. The Management Company may own a minority interest in the UOL Partnership and/or be named as the "manager" or general partner of such a Partnership.

389. In some cases, the same entity acts as both the Syndicator and the Management Company.

390. The Management Company's function is to control the day-to-day operations of the UOL Partnership so that the urologists will not need to or be required to perform any services for the UOL Partnership.

391. In effect, all of the UOL Partnership's operations are outsourced to the Management Company.

392. The Management Company arranges for the delivery of the lithotripter and a skilled technician, trained in the use of the lithotripter, to a Host Hospital, handles the scheduling and the billing of the per procedure fees to the Host Hospital as well as collecting the fee from the Host Hospital.

393. The Management Company receives a percentage of the revenue received by the UOL Partnership as its management fee. Accordingly, the Management Company will share in any kickbacks received by the UOL Partnership.

The UOL Partnership as a Shell Entity

394. Either the Syndicator or the Management Company has a minority interest in the UOL Partnership. Urologists own a majority interest in the UOL Partnerships.

395. Due to provisions in the operating agreements or other governing documents for the UOL Partnerships, it is the Syndicator, the Management Company, or a representative of either the Syndicator or the Management Company that has the power to bind the UOL Partnership to contracts. The Urologists do not have such power.

396. The Urologists do not participate in the management of the Urology Owned Lithotripsy Partnership and can vote only on a few limited matters such as the merger or sale of the Partnership.

397. The UOL Partnerships are passive investment vehicles for physicians who wish to earn above market rates of return merely by investing in a "shell" company that owns a lithotripter and earns revenue by charging Host Hospitals a per procedure fee for providing the Host Hospitals with a lithotripter and the services of a technician (who may be an employee of the Management Company) to operate the lithotripter.

398. Requirements in the governing documents for the UOL Partnership ensure that the Urologist Owners of the UOL Partnership will be in the position to generate lithotripsy business for a Host Hospital and also be a source of other significant federal program health care business for the Host Hospital.

399. An UOL Partnership typically requires its members: (i) to be licensed to practice medicine in the state in which such Partnership contracts with Host Hospitals; (ii) to remain eligible for participation in Medicare or Medicaid and health care programs operated by the state in which the UOL Partnership has contracts with Host Hospitals; (iii) to maintain active membership on the medical staff of a hospital; and (iv) to not own an interest in any other lithotripsy partnership.

The Role of Urologist Owners

400. There is no reasonable business purpose for a Syndicator to require that numerous urologists own the UOL Partnerships.

401. The only purpose for urologist ownership is to use the Urologist Owners to market the services provided by the Syndicator and Management Company and to coerce the Host Hospitals to enter into exclusive agreements with the UOL Partnership.

402. By using their leverage with the Host Hospitals and threatening to take all their business elsewhere, the Urologist Owners of an UOL Partnership are able to obtain per procedure payments that are not at fair market value.

403. Relator has knowledge of situations in which Urologist Owners have acted on their threat by taking their business to neighboring hospitals and ASCs.

404. Additionally, the per procedure payments are set at a rate that reflects the volume and the value of the business generated by the Urologist Owners for Host Hospitals.

405. These per procedure payments are so generous that the net income of an UOL Partnership can be more than 50% of its gross revenue.

406. The Urologist Owners perform the professional component of the lithotripsy procedures. These services are performed through such owners' medical practice and are not performed for the UOL Partnership.

Urologist Owners Refer Unnecessary Services

407. The medical judgment of the Urologist Owners has been affected by the existence of this financial arrangement between the UOL Partnerships and the Host Hospitals.

408. Urologist Owners refer more lithotripsy treatments than urologists who do not own an interest in an UOL Partnership. At least one published research study has confirmed that Urologists who own an interest in an ambulatory surgical center ("ASC") perform more lithotripsy procedures than Urologists who do not own such an interest. Furthermore, as Urologists who own interests in ASCs penetrate a market, the number of lithotripsy procedures increase dramatically.

409. Additionally, during a lithotripsy procedure Urologist Owners many "under perform" the lithotripsy, allowing part of the kidney stones to remain, in order to ensure the patient returns for an additional treatment.

410. Urologist Owners also provide lithotripsy to patients without kidney stones. These patients typically have symptoms associated with kidney stones but an ultrasound has not conclusively shown the presence of a stone. Nevertheless, Urologist Owners will perform lithotripsy on these patients.

411. The Relator has had discussions with John Tobin, a skilled lithotripsy technician about numerous lithotripsy procedures in which he operated the lithotripter and in which the kidney itself was bombarded with shockwaves in an effort to break up a stone that did not exist.

412. The patient's long-term health is adversely affected by bombarding the soft kidney tissue with shockwaves.

413. The Relator has also had discussions with John Tobin and Deb Eckert, lithotripsy technicians working for UMS and UST about the treatment of these "pseudo" stones and stones too small to treat. These are common practices.

414. The Urologists' ownership in the UOL Partnerships and the extraordinary profits they receive from the ownership provides the motivation to over utilize lithotripsy, even if it is medically unnecessary.

Billing and Payments for Lithotripsy

415. The Host Hospitals bill Medicare and Medicaid for the facility fee for the lithotripsy procedure with the Host Hospital being entitled to the facility fee paid by Medicare and Medicaid. The Host Hospital also bills any third-party health insurer for the lithotripsy services it furnishes.

416. The professional service fee of the urologist performing the procedure is billed separately to Medicare and Medicaid.

417. The Host Hospital pays the UOL Partnership a per procedure fee for the use of the lithotripsy equipment and the technician.

418. The UOL Partnership pays the Management Company a percentage of the fees it receives from the Host Hospital as a management fee.

419. If the Syndicator is a member of the UOL Partnership, then it receives a share of the profits of the UOL Partnership, which profits are based solely on the payments made to such partnership by Host Hospitals.

THE PARTICIPANTS' KNOWLEDGE OF THE ILLEGAL SCHEME[1]

420. Prior to accepting an investment from an urologist, the Syndicator and/or the UOL Partnership provide each potential investor with a Private Placement Memorandum ("PPM"). The PPM advises potential investors of the regulatory compliance risks inherent in this scheme.

421. Specifically, the PPM advises investors that the UOL Partnership and the Host Hospitals that it does not comply with the Investment Interest Safe Harbor to the federal Anti-kickback Statute because, among other things, the Urologists, all of whom were in a position to make referrals to a Host Hospital for lithotripsy and to generate other business for the Host Hospital, own more than forty (40%) of the value of the investment interests in the UOL Partnerships. Thus, it is known the Investment Safe Harbor does not apply.

422. The PPM also advises the Urologists that the agreement with the Host Hospitals would not meet the elements of the Equipment Rental Safe Harbor because the contract between the Host Hospitals and the UOL Partnerships has a variable element in that rent or fees were charged on a per-procedure or per-click basis. Accordingly, it is known that such rent or fees are not set in advance and do not qualify under the Equipment Rental Safe Harbor.

423. The PPM also advises the Urologists that the arrangement with Host Hospitals would not qualify for the ***Personal Services and Management Contracts Safe Harbor*** to the

[1] The scheme described herein violates both the federal Anti-kickback Act and the Stark Law. The requirements of the federal Anti-kickback Statute and the requirements of the Stark Law are discussed in detail below.

federal Anti-kickback Statute because of the per-procedure payments being made to the UOL Partnership.

424. The PPM also addresses Stark compliance, advising potential investors that they would not be able to make referrals to a Host Hospital for inpatient and outpatient services unless all of the direct and indirect financial relationships between the investor, the UOL Partnership, and the Host Hospitals satisfied an applicable exception to Stark II.

425. The PPM was prepared under the direction of the Syndicator and the Management Company and/or was reviewed by and approved by the Syndicator and the Management Company

426. The Syndicator and the Management Company each have knowledge that the arrangement had to comply with the federal Anti-kickback Statute and Stark.

427. Either the Syndicator or the Management Company negotiates the per-procedure fees that the Host Hospitals pay to the UOL Partnerships, which fees are set at a rate that is not consistent with fair market value.

428. The total fees paid by the Host Hospitals vary with the volume of lithotripsy procedures performed by the Host Hospital.

THE UMS-GLL VENTURE

429. UOL Partnerships were created around the country by various Syndicators.

430. The Relator worked for UMS, a Syndicator that set up dozens of UOL Partnerships throughout the United States, and also worked extensively with Great Lakes Lithotripsy, LLC ("GLL"), the UOL Partnership that UMS set up in Michigan.

431. UMS, a Syndicator, became interested in delivering mobile lithotripsy services in Michigan around 2001 and organized GLL for the purpose of contracting with Michigan hospitals to provide them with lithotripsy equipment and skilled lithotripsy technicians.

432. GLL initially successfully operated from 2001 to 2005 without physician ownership but was later opened to physician ownership.

433. UMS decided to syndicate interests in GLL and began a campaign to recruit urologists who practiced in Michigan.

434. Opening GLL to urologist ownership was calculated strategy used by UMS to secure contracts with additional hospitals to obtain the required CON necessary to expand GLL's mobile lithotripsy routes by adding new host sites and providing additional lithotripters.

435. At the time UMS, as the Syndicator, began recruiting physician owners, GLL was solely owned by UMS and was able to provide lithotripsy equipment, personnel and management services without any physician ownership.

436. UMS offered membership interests in GLL at attractive rates to the urologists, promising rates of return so high that the urologists would be able to completely recoup the purchase price of their membership interest in GLL within the first year of purchasing such interest.

437. Once these membership interests were sold, urologists owned seventy-five percent (75%) (as Class B membership interests) of GLL and UMS owned the remaining twenty-five percent (25%) (as Class A membership interests).

438. Such physician ownership began in 2005 and has continued to the present.

439. The Management Company for GLL is UMS-LM, a wholly owned subsidiary of UMS. It conducts, supervises, and manages the day-to-day operations of GLL such as billing, scheduling of equipment leasing and personnel, collection of revenues, disbursement of funds, obtaining supplies and services, marketing and promotion of GLL and providing such other services as are required for the efficient operation of GLL.

440. UMS-LM helped UMS negotiate the contracts with the GLL Host Hospitals and set the fees to be paid by such Host Hospitals. Additionally, UMS-LM managed the day-to-day operations of GLL, developing personnel procedures and policies; developing administrative procedures for collection of accounts receivable, collecting the fees from the Host Hospitals, servicing the lithotripsy equipment, arranging for the delivery of the lithotripsy equipment to the Host Hospitals and hiring the skilled technicians.

441. UMS caused GLL to enter into the management agreement with UMS-LM by controlling the Board of Directors of GLL. The physician owners of GLL did not have any right to approve the management agreement with UMS-LM, except indirectly by having the ability to vote for one out of the three directors on the Board of Directors of GLL. Only a majority vote of the Board of Directors would have been required to approve the contract with UMS-LM. Additionally, Jorgen Madsen, as President of GLL, had the authority to unilaterally bind GLL to contracts.

442. UMS-LM collects a management fee that is fixed at ten (10%) percent of GLL's revenue. UMS-LM thus shares in any kickback received by GLL.

Quid Pro Quo Referral Scheme

443. Since Michigan requires that a certificate of need be issued prior to a company bringing a lithotripter into Michigan or expanding the use of an existing lithotripter, UMS recruited Urologists to invest in GLL so that the urologists could leverage their control over referrals for inpatient and outpatient urology services to convince the hospitals at which they were on staff to commit inpatient discharge data to a certificate of need application filed in the name of GLL.

444. The certificate of need requirements do not mandate physician ownership of the lithotripsy company nor does Michigan state law.

445. In order to secure a certificate of need in Michigan, the state of Michigan must receive data exhibiting the need for the particular services or must takeover a contract already in place.

446. In the case of lithotripsy, the state needed inpatient discharge data on how many lithotripsy procedures were performed by the hospital during a specified period.

447. Once a GLL Host Hospital pledged inpatient discharge data to a specific lithotripsy project, it was prohibited from pledging that same inpatient discharge data to another lithotripsy project. Accordingly, prior to pledging such data, the GLL Host Hospitals agreed to the terms and conditions of a lithotripsy services agreement titled a "Host Site Agreement" with GLL.

448. The GLL Urologists were specifically recruited by UMS so that such Urologists would secure the GLL Host Hospitals' lithotripsy business for GLL by threatening to take all of their health care business elsewhere.

449. As part of its scheme, UMS intended to and did recruit over 140 urologists, each of whom practiced at a hospital that UMS was targeting for participation in a UMS-GLL Venture.

450. UMS required that the physician investors in GLL be licensed to practice medicine in Michigan, remain eligible for participation in Medicare or Medicaid and any Michigan-operated health care program, maintain active membership on the medical staff of a hospital accredited by JCAHO or another recognized national accreditation agency, and to not own an interest in another lithotripsy business.

451. The purpose of these requirements was to ensure that the physician owners of GLL would be in a position to refer patients to a Host Hospital for lithotripsy and also be a source of other significant federal health care program business for the Host Hospitals.

452. This calculated strategy of recruiting urologists to invest in GLL permitted UMS to use the urologists to secure business from the targeted hospitals and permitted the urologists which controlled all other referrals to the hospital to extract above fair market value fees for lithotripsy.

453. GLL's Urologist Owners coerced hospitals where they were on staff (or to which they made referrals for urological services) to contract with GLL by threatening to stop referring patients to the hospital for any urological services including lithotripsy, inpatient services and outpatient services.

454. In order to keep these referrals for inpatient and outpatient hospital services, the GLL Host Hospitals entered into agreements with GLL that permitted the GLL Host Hospitals to offer lithotripsy under arrangements with GLL.

Knowledge of the Participants in the UMS-GLL Venture

455. In a Private Placement Memorandum ("GLL PPM"), UMS advised the urologists it recruited that in order for an urologist owner of GLL to make a referral to a Host Hospital for designated health services, the relationship between GLL and the GLL Host Hospitals would have to meet an applicable Stark exception.

456. The GLL PPM also advised urologists considering an investment in GLL that the arrangement between GLL and a Host Hospital does not qualify for a safe harbor to the federal Anti-kickback Statute.

457. The Defendant GLL Urologists, GLL, UMS, UMS-LM and the Host Hospitals were also well aware that the arrangement between GLL and the Host Hospitals created a forbidden indirect financial relationship between the urologists, as owners of GLL, and each GLL Host Hospital because the fees being paid for the equipment and services provided by GLL were per-procedure fees that would vary with the volume of business generated between the parties.

458. In the case of GLL, the financial relationship between the Urologist Owners of GLL and the Host Site Hospitals does not qualify for a Stark exception.

459. Accordingly, an Urologist Owner of GLL cannot refer a patient to a GLL Host Hospital without violating Stark.

460. The Urologist Owners of GLL have all made thousands of referrals to Host Hospitals for inpatient and outpatient services, DHS, in violation of Stark.

461. The arrangement does not qualify for a safe harbor to the federal Anti-kickback Statute and since one purpose of the arrangement was to induce referrals, the arrangement violates federal the Anti-kickback Statute (section 1128B(b) of the Act).

462. All payments made by the GLL Host Hospitals to GLL are kickbacks.

463. All distributions received by the GLL Urologists from GLL are kickbacks.

464. All distributions received by UMS from GLL are kickbacks.

465. All payments received by the GLL Host Hospitals for the inpatient and outpatient services referred by the GLL Urologists are kickbacks.

466. All management fees collected by UMS-LM are kickbacks.

THE AKSM-GML VENTURE

467. Another Syndicator, AKSM, acts as both the Syndicator and the Management Company for an arrangement in which Defendant Greater Michigan Lithotripsy, LLC ("GML") is the UOL Partnership.

468. GML has a management agreement with AKSM pursuant to which AKSM shares in a percentage of the revenue earned by GML and thus AKSM shares in any kickbacks received by GML.

469. AKSM offered membership interests in GML at attractive rates to urologists, promising high rates of return so high that the urologists who invest in GLM earn enough to recoup the purchase price of their membership interest in GML in a short period of time.

470. Collectively, the Defendant GML Urologists own 70% of the membership interests in GML, Defendant Beaumont Hospital owns 10% of the membership interests, Defendant Spectrum owns 10% of the membership interests and AKSM owns 10% of the membership interests.

471. Such physician and hospital ownership began in 2005 or 2006 and has continued to the present.

472. AKSM negotiates the contracts with the GML Host Hospitals and sets the fees to be paid by the GML Host Hospitals to GML. Additionally, AKSM manages the day-to-day operations of GML, developing personnel procedures and policies; developing administrative procedures for the collection of accounts receivable, collecting the fees from the GML Host Hospitals, servicing the lithotripsy equipment, arranging for the delivery of lithotripsy equipment to the GML Host Hospitals and hiring the skilled technicians.

473. AKSM requires that the physician investors in GML be licensed to practice medicine in Michigan, remain eligible for participation in Medicare or Medicaid, maintain active membership on the medical staff of a hospital, and not own an interest in another lithotripsy company providing lithotripsy equipment to hospitals.

474. The purpose of these requirements was to ensure that the physician owners of GML would be in a position to refer patients to a Host Hospital for lithotripsy and also be a source of other significant federal health care program business for the Host Hospitals.

475. As the Management Company, AKSM conducts, supervises, and manages the day-to-day operations of GML such as billing, scheduling of equipment leasing and personnel, collection of revenues, disbursement of funds, obtaining supplies and services, marketing and promotion of GML and providing such other services as are required for the efficient operation of GML.

476. AKSM approved the contracts between GML and the Defendant GML Host Hospitals, knowingly causing GML to enter into an arrangement that violated the federal Anti-kickback Statute and Star.

477. AKSM collects a management fee that is a percentage of the revenue received by GML. AKSM thus shares in any kickback received by GML.

Quid Pro Quo Referral Scheme

478. AKSM, due to Michigan's certificate of need requirements, began recruiting urologists to invest in GML so that the urologists could leverage their control over referrals for urology services to convince the hospitals at which they were on staff to commit inpatient discharge data to a certificate of need application specifying GML as the host services coordinator.

479. Neither the certificate of need requirements nor Michigan law requires that the owners of GML be licensed physicians.

480. The GML Host Hospitals agreed to the terms and conditions of a lithotripsy services agreement ("Services Agreement") with GML during the process of submitting an application for a certificate of need. The Services Agreements required GML to provide lithotripsy equipment and a skilled technician to the Defendant GML Host Hospitals in exchange for a per procedure fee to be paid by the GML Host Hospitals.

481. AKSM needed the support of the urologists to convince hospitals to commit inpatient discharge date to the mobile lithotripsy routes that AKSM and/or GML had proposed and to agree to enter into the Services Agreements with GML.

482. Dr. Mertz, a urologist investor in GML, actively tried to get a hospital known in 2005-2006 at Bon Secours and Cottage Hospital to terminate its contract with GLL to contract with GML.

483. When Bon Secours could not do so, Dr. Mertz transferred his referrals for lithotripsy and other urological services to Beaumont.

484. Dr. Campbell and Dr. Telang, both GML affiliated Urologists, also transferred their referrals for lithotripsy and other urological services to Beaumont.

485. As part of its scheme, AKSM intended to and did recruit close to a hundred urologists who practiced at a hospital that AKSM was targeting for participation in a AKSM-GML Venture.

486. This calculated strategy of recruiting urologists to invest in GML permitted AKSM to use the urologists to secure business from the targeted hospitals other than Beaumont or Spectrum.

487. The Defendant GML Urologists coerced the Defendant GML Host Hospitals where they were on staff (or to which they made referrals for urological services) to contract with GML by threatening to stop referring patients to such Host Hospitals for any urological services including lithotripsy.

488. Beaumont and Spectrum, as members of GML at the time AKSM began recruiting urologists to invest in GML, were aware that the urologists were coercing the other GML Host Hospitals to enter into contracts with GML.

489. In order to keep these referrals for inpatient and outpatient hospital services, the Defendant GML Host Hospitals entered into exclusive agreements with GML that permitted the Defendant GML Host Hospitals to offer lithotripsy under arrangements with GML.

490. GML also has arrangements pursuant to which it provides lasers and technicians to operate them to treat stones.

491. GML also has arrangements pursuant to which it offers cryotherapy equipment and services to hospitals and, upon information and belief, is furnishing DHS to one or more of the GML Host Hospitals.

Knowledge of the Participants in the AKSM-GML Venture

492. In a Private Placement Memorandum (AKSM PPM), AKSM advised the Defendant GML Urologists that in order for any of them to make a referral to a Host Hospital for designated health services, the relationship between them, Defendant GML and the Defendant GML Host Hospitals would have to meet an applicable Stark exception.

493. The AKSM PPM also advised the Defendant GML Urologists that the arrangement between the GML investors, GML and a GML Host Hospital would not qualify for a safe harbor to the federal Anti-kickback Statute.

494. AKSM and each of the Defendant GML Host Hospitals were also well aware that the arrangement between GML and the GML Host Hospitals created an indirect financial relationship between the Defendant GML Urologists, as owners of GML, and each GML Host Hospital and that the fees being paid for the equipment and services provided by GML were per-procedure fees that would vary with the volume of business generated between GML and the Defendant GML Host Hospitals.

495. Defendant GML may have entered into a circumvention scheme with the GML Host Hospitals pursuant to which the GML Host Hospitals agreed to refer patients for lithotripsy to GML in order to get the physician owners of GML to continue to refer patients to the Host Hospitals for other inpatient and outpatient services.

496. In the case of GML, the financial relationship between the Urologist Owners of GML and the Defendant GML Host Hospitals does not qualify for a Stark exception.

497. The arrangement does not qualify for a Stark exception because, among other things, Beaumont and Spectrum, each of whom own an interest in GML and have high volumes of lithotripsy procedures, pay per-procedure fees to GML that are significantly higher than the per-procedure fees paid by the GML Host Hospitals who do not own membership interests in GML. Accordingly, the aggregate charge for rental of the lithotripter and the technician vary as a function of the value and volume of the business between the parties.

498. Accordingly, a GML Urologist cannot refer a patient to a GML Host Hospital for DHS without violating Stark.

499. The arrangement does not qualify for a safe harbor to the federal Anti-kickback Statute, because among other things, one purpose of the arrangement was to induce referrals.

500. The arrangement does not qualify for a safe harbor to the federal Anti-kickback statute because, among other things, the aggregate charge for the rental of the lithotripter and the technician vary as a function of the value and volume of the business between the parties.

501. The aggregate charge also is higher to GML Host Hospitals that are members of GML than GML Host Hospitals that are not members, disqualifying the arrangement from safe harbor protection.

502. Accordingly, the arrangement violates federal the Anti-kickback Statute (section 1128B(b) of the Act).

503. All payments made by the GML Host Hospitals to GML are kickbacks.

504. All distributions received by the GML Urologists from GML are kickbacks.

505. All distributions received by AKSM, Beaumont and Spectrum from GML are kickbacks.

506. All payments received by the GML Host Hospitals for the inpatient and outpatient services referred by the GML Urologists are kickbacks.

507. All management fees collected by AKSM are kickbacks.

REGULATORY FRAMEWORK

508. Ms. Mitchell brings this *qui tam* action in the name of the United States of America, the State of Illinois, the State of Indiana, and the state of Michigan against the Defendants jointly and severally.

509. This is an action pursuant to the False Claims Act, 31 U.S.C. §3729 *et seq.* ("FCA") to recover damages and civil penalties for false statements and claims that defendants made or presented to the United States, and the State of Illinois, the State of Indiana, and the state of Michigan.

510. The violations arise out of Defendants' requests for payment by Medicare and Medicaid and to the federal and state health care programs (hereinafter, the "U.S. Government" or "U.S." – which includes the States of Illinois, Indiana, Michigan and other states) based on false claims for hospital services including lithotripsy. The false claims arise out of violation of self-referral prohibitions and anti-kickback laws, as more fully set forth below.

511. The Defendant Host Hospitals, with actual knowledge, and with either reckless disregard or deliberate ignorance of their obligations, submitted thousands of claims to Medicare, Medicaid or other federally funded programs and thousands of claims to commercial third party payors for lithotripsy, inpatient services and outpatient services provided pursuant to a prohibited referral.

512. The Defendant Host Hospitals, with actual knowledge, and with either reckless disregard or deliberate ignorance of their obligation to not pay for referrals, agreed to enter into a *quid pro quo* arrangement with a Defendant UOL Partnerships to exchange referrals for inpatient and outpatient services for their agreement to contract with UOL Partnerships for the provision of lithotripsy equipment and technicians.

513. The Urologist Owners, with actual knowledge and reckless disregard of their obligations, to not make referrals to a DHS entity with which they have a financial relationship, have made such prohibited referrals.

Medicare and Medicaid Programs

514. The Medicare Program is a health insurance program for individuals 65 years and older, certain disabled individuals under age 65, and people of any age who have permanent kidney failure. The Medicare statute is codified at 42 U.S.C. § 1395 (Title XVIII of Social Security Act, 42 U.S.C. § 483.1 *et seq.*).

515. The Medicare program is administered through the U.S. Department of Health and Human Services ("HHS"), an agency within the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS.

516. The Medicaid Program is a joint federal-state program funded under Title XIX of the Social Security Act. 42 U.S.C. § 1396 *et seq.* As a prerequisite to enrollment as a provider in

the Medicaid Program, hospitals are required to enter into provider agreements and agree, among other things, to comply with federal and state provider participation requirements as a condition of federal and state funding. 42 U.S.C. § 1396a(w).

517. Outpatient hospital claims are paid pursuant to a Medicare reimbursement schedule.

518. Ambulatory Surgical Center ("ASC") claims are paid pursuant to Part B of the Medicare program and are paid according to a fixed schedule for services.

519. According to 42 U.S.C. § 1320a-7b(f)(1), federal health care programs include any plan or program that provides health benefits directly or indirectly through insurance or otherwise funded directly or in part by the United States Government.

THE FEDERAL ANTI-KICKBACK STATUTE

520. In 1972, Congress enacted the federal health care Anti-kickback Statute, 42 U.S.C. § 1320a-7b *et seq*., which prohibited payments, directly or indirectly designed to induce a person to refer or recommend services that may be paid for by federal government.

521. The federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b), establishes criminal penalties, including fines and treble damages, with respect to any person who knowingly offers, pays, solicits, or receives any remuneration to induce or in return for (1) purchasing, (2) ordering, (3) arranging for purchasing or ordering, and/or (4) recommending the purchasing or ordering of any goods payable under federal health care programs.

522. While concerns about increased costs and over utilization of health care services are at the heart of the Anti-kickback Statute, it is not necessary that these factors be present or proven for a violation of the statute to be found.

523. Where remuneration is paid purposefully to induce rewards or referrals of items and services payable by any federal health care program, the Anti-kickback Statute is violated.

Remuneration includes anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

524. The federal Anti-kickback Statute imposes liability to parties on both sides of an impermissible "kickback" transaction.

525. The federal Anti-kickback Statute applies to any arrangement where even one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.

526. The federal Anti-kickback Statute can be violated where remuneration is tied to referrals even if the referrals were for medically necessary services.

527. The HHS Office of Inspector General has enacted several regulations, known as "Safe Harbors" setting forth the terms and conditions that immunize an arrangement from liability under the Anti-kickback Statute.

528. These regulations set forth Safe Harbors applicable to investment interests, equipment rental arrangements, and personal service and management contract arrangements.

529. An arrangement that fails to satisfy each and every Safe Harbor element is not immunized by the Safe Harbor. Such an arrangement is not illegal *per se*, however, it will be illegal if there is an intent to induce referrals.

530. Where a hospital pays a physician owned entity, that generates business for the hospital, a per procedure fee that is not at fair market value, such fee is a kickback.

531. Factors that demonstrate a violation of the Anti-kickback Statute by Syndicators, Management Companies, UOL Partnerships, Urologist Owners, and Host Hospitals include:

(i) The payments for lithotripsy services on a per procedure basis;

(ii) Per procedure fees that were not set at fair market value;

(iii) Revenue flowing to the UOL Partnership reflects the value or volume of business generated between the Urologist Owners, the UOL Partnership and the Host Hospitals;

(iv) The exclusivity of the relationship between a specific UOL Partnership and the Host Hospital under contract to it;

(v) The Urologist Owners are in a position to generate referrals for lithotripsy and other health care services or otherwise generate business for a Host Hospital; and

(vi) The tying of referrals for lithotripsy to referrals for inpatient and outpatient services and other DHS and the coercion exerted by the Urologist Owners on a Host Hospital to enter into an exclusive arrangement for lithotripsy services.

532. The arrangement between the Urologist Owners and the UOL Partnerships does not qualify for the ***Investment Safe Harbor*** to the Anti-kickback Statute because, among other things, the Urologist Owners own more than 40% of the interests in the UOL Partnerships.

533. The arrangement between the UOL Partnership and the Host Hospitals does not qualify for the ***Equipment Rental*** or the ***Personal Services*** and ***Management Agreement Safe Harbors***.

534. To qualify for the ***Equipment Rental Safe Harbor***, among other things, the lithotripsy arrangement must comply with the following:

(i) The rental charges must be consistent with fair market values (42 C.F.R. § 1001.952(c)(5));

(ii) The per procedure rental charges cannot take into account the value or volume of any referrals or other business generated by the Urologist Owners and the Host Hospitals (42 C.F.R. § 1001.952(c)(5); and

(iii) The agreement must be commercially reasonable even if no referrals were made between the parties (42 C.F.R. § 1001.952(c)(6)).

535. Each of the lithotripsy ventures described herein fails to qualify for such Safe Harbors because the rent paid is not consistent with fair market value, the rent varies with the volume of business generated by the Host Hospital for the UOL Partnership, and because the agreement is not commercially reasonable in the absence of any referrals between the parties.

536. The federal False Claims Act provides that those who knowingly and willfully make or cause to be made any false statement or representation of a material fact in any application for any benefit or payment from the federal government is liable for a civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the federal government sustains because of those acts. 31 U.S.C. § 3729(a).

THE STARK LAW

537. In 1989, Congress granted the Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), the power to enforce prohibitions on physicians referring Medicare patients for designated health services to entities in which those physicians have a financial interest. Those prohibitions are codified in 42 U.S.C. §1395nn and are often referred to as the "Stark Law," after U.S. Representative Pete Stark, who introduced the legislation.

538. Federal regulations also provide that that a physician or entity entering into any arrangement or scheme who knows, or should know, that the arrangement has a principal purpose of circumventing the prohibition on referrals set out in the Stark law shall be punishable by a civil monetary penalty of $100,000. 42 C.F.R. §§1003.102(b)(10) and 1003.103(b).

539. In 1993, the Stark Law was amended to, among other things, also apply to Medicaid patients. The 1993 amendment of Stark Law is often referred to as "Phase II" of the Stark Law.

540. The Stark Law II Phase II Regulations were published on March 26, 2004, and became effective on July 26, 2004. 69 *Federal Register* 16054-16146 (March 26, 2004).

541. The Stark Law II Phase II Regulations set forth several exceptions to the Stark self-referral prohibition.

542. The Stark II Phase II Regulations include exceptions that are similar (but not identical) to the Anti-kickback Statute for rental of equipment, 42 C.F.R. § 411.357 (b)(1)-(6) fair market value arrangements, and indirect compensation arrangements.

543. Non-compliance with a Stark Law exception renders a claim for payment illegal *per se*.

544. Although lithotripsy itself is not a DHS, the arrangement between the UOL Partnership and the Host Hospitals creates a financial relationship between the Urologist Owners and the Host Hospitals.

545. Such an indirect compensation arrangement is subject to the Stark Law.

546. The Stark Law prohibits an Urologist Owner from making any referrals for designated health services unless the arrangement between the Urologist Owners and the UOL Partnership in which such urologists own an interest and the Host Hospitals under contract to the UOL Partnership qualifies for a Stark Law exception.

547. Moreover, it is CMS policy that any DHS referrals made to a Host Hospital by a Urologist Owner of an UOL Partnership are prohibited by Stark unless the arrangement between such UOL Partnership and the hospital qualifies for a Stark exception.

548. The Urologist Owners have an indirect compensation arrangement with a Host Hospital that entered into a lithotripsy services agreement with their UOL Partnership.

549. Where the compensation arrangement between the Host Hospital and the UOL Partnership is considered a lease of equipment, there are three potentially applicable Stark exceptions: (i) the ***Equipment Lease Exception*** set forth at § 411.357(b); (ii) the ***Fair Market Value Exception*** set forth at § 411.357(l); and (iii) the ***Indirect Compensation Exception*** set forth at § 411.357(p).

550. To qualify for the ***Equipment Rental Exception or the Fair Market Value Exception***, among other things; the lithotripsy arrangement must comply with the following:

a. The rental charges must be consistent with fair market values (42 C.F.R. § § 311.457(b)(4), 311.457(l)(3));

b. The per procedure rental charges or fees cannot take into account the value or volume of any referrals or other business generated by the Urologist Owners and the Host Hospitals (42 C.F.R. § § 411.357(b)(4), 411.357(l)(3);

c. In the case of the ***Equipment Rental Exception***, the agreement must be commercially reasonable even if no referrals were made between the parties (42 C.F.R. § 411.357(b)(5)) or, in the case of the ***Fair Market Value Exception***, the agreement must be commercially reasonable and further the legitimate business purposes of the parties (42 C.F.R. § 411.357(l)(4)).

551. The lithotripsy arrangements described herein fail to qualify for either the ***Equipment Rental Exception*** or the ***Fair Market Value Exception*** because the rent paid is not consistent with fair market value, the rent varies with the volume of business generated by the Host Hospital for the UOL Partnership, and because the agreement is not commercially reasonable.

552. In addition, such financial arrangements do not qualify for a ***Fair Market Value Exception or an Indirect Compensation Exception*** because the arrangement violates federal the Anti-kickback Statute (section 1128B(b) of the Act) and the services to be performed under the arrangement involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

553. Finally, in an arrangement in which the physician performing lithotripsy and is an independent contractor of the UOL Partnership, the ***Personal Services Exception*** to Stark is also potentially applicable.

554. On or after October 1, 2009, if the arrangement between GLL and the Host Hospital is viewed as an equipment lease, the arrangement *per se* would not qualify for the ***Equipment Rental Exception*** because all leases between GLL and the Host Hospitals were based on a per procedure fee. Accordingly, such leases were "per click" leases and the compensation paid varied based upon patients referred between the parties which are prohibited under Stark.

555. The referrals for DHS that Urologist Owners make to a Host Hospital under contract with an UOL Partnership violate the Stark Law.

556. As a condition of participation in the Medicare program and as a condition precedent to the receipt of payment or reimbursement from Medicare of costs incurred for treating and providing care to Medicare beneficiaries, each Host Hospital and Urologist completed cost reports that contained certifications that it was familiar with the laws and regulations regarding the provision of healthcare services, and that the services identified in the cost reports were provided in compliance with Medicare laws and regulations.

557. Based on Medicare regulations and laws cited herein, if costs or expenses are billed to Medicare through the submission of false cost reports, then the cost reports are false claims to Medicare because they are based on fraudulent activities and billings of Defendants.

558. The Defendants knowingly and intentionally planned and initiated the above-described scheme to circumvent and violate healthcare fraud and obtain and/or inflate payments from the U.S. that the U.S., but for the false statements, would not have paid. This fraudulent maximization of federal reimbursement resulted in higher income, salary, bonuses and other payments to each Defendant. The above-listed knowing and/or reckless violations of the Stark Law and the anti-kickback acts rendered Defendants out of compliance with both Medicare and Medicaid, and ineligible to receive Medicare and/or Medicaid reimbursements for services.

559. Accordingly, all reimbursement claims submitted to Medicare and/or Medicaid were improper and fraudulent.

AKS and Stark Applied to the UMS-GLL Venture

560. In this case, the Defendant GLL Host Hospitals knowingly and willfully offered and paid remuneration to the Defendant GLL Urologists by way of contracting with GLL, a company owned by the Defendant GLL Urologists, for the provision of lithotripsy services and made payments for such lithotripsy services that exceeded fair market value for such services and that reflected the volume and/or value of business generated between by the GLL Urologists and the GLL Host Hospitals.

561. Additionally, the payments made by the GLL Host Hospitals to GLL were made to induce referrals of other health care business from the GLL Urologists to the GLL Host Hospitals.

562. The GLL Urologists coerced the Defendant GLL Host Hospitals into contracting with GLL to perform lithotripsy as a mobile service by threatening to take both their federal healthcare business and their private pay healthcare business elsewhere if the Defendant GLL Host Hospitals would not enter into contracts with GLL.

563. By falsely billing, as set forth in this Complaint, the Defendant GLL Host Hospitals knowingly receive payments from the U.S. that were kickbacks.

564. Defendant GLL receives kickbacks from the Defendant GLL Host Hospitals as payments for referral health care business paid by federal health care programs to the Defendant Host Hospitals.

565. The Defendant GLL Urologists, UMS, and UMS-LM, each of whom knowingly participated in actively facilitating the arrangement that provided these kickbacks, share in these kickbacks through profit distributions from GLL and management fees paid to UMS-LM.

566. The indirect financial relationship between the GLL Urologists and the Host Hospitals does not qualify for a Stark Law exception.

567. The GLL Urologists cannot make referrals for DHS to a GLL Host Hospital.

568. The GLL Urologists make such prohibited referrals.

569. The GLL Host Hospitals bill for such prohibited referrals.

570. The payments received by the GLL Host Hospitals for any inpatient and outpatient services referred by a GLL Urologist are illegal under Stark.

AKS and Stark Applied to the UMS-Mishawaka Venture

571. In this case, the Defendant Mishawaka Host Hospitals knowingly and willfully offered and paid remuneration to the Defendant Mishawaka Urologists by way of contracting with UMS-Mishawaka, a company owned by the Defendant Mishawaka Urologists, for the

provision of lithotripsy services and made payments for such lithotripsy services that exceeded fair market value for such services and that reflected the volume and/or value of business generated between the Mishawaka Urologists and the Mishawaka Host Hospitals.

572. Additionally, the payments made by the Mishawaka Host Hospitals to UMS-Mishawaka were made to induce referrals of other health care business from the Mishawaka Urologists to the Mishawaka Host Hospitals.

573. At the times relevant to this Complaint, Dr. Stephen P. Guss and Dr. Scott Rutchik were the only urologists employed at St. Joseph Community Hospital of Mishawaka.

574. Accordingly, they controlled referrals for urological services to St. Joseph Community Hospital of Mishawaka.

575. Drs. Guss and Rutchik own 66.67% of the membership interests in UMS-Mishawaka.

576. UMS-LM owns 33.33% of the membership interests in UMS-Mishawaka.

577. UMS-LM also manages the day-to-day operations of UMS-Mishawaka.

578. The Mishawaka Urologists coerced the Defendant Mishawaka Host Hospitals into contracting with UMS-Mishawaka to perform lithotripsy as a mobile service.

579. By falsely billing, as set forth in this Complaint, the Defendant Mishawaka Host Hospitals knowingly received payments from federal health care programs that were kickbacks.

580. Defendant UMS-Mishawaka receives kickbacks from the Defendant Mishawaka Host Hospitals as payments for referring health care business paid by federal health care programs to the Defendant Mishawaka Host Hospitals.

581. The Defendant Mishawaka Urologists, UMS, and UMS-LM, each of whom share in these kickbacks, participated in actively facilitating the arrangement that provided these kickbacks.

582. The indirect financial relationship between the Mishawaka Urologists and the Mishawaka Host Hospitals does not qualify for a Stark exception.

583. The Mishawaka Urologists cannot make referrals for DHS to a Mishawaka Host Hospital.

584. The Mishawaka Urologists make such prohibited referrals.

585. The Mishawaka Host Hospitals bill for such prohibited referrals.

586. The payments received by the Mishawaka Host Hospitals for any inpatient and outpatients services referred by a Mishawaka Urologist are illegal under Stark.

AKS and Stark Applied to the AKSM-GML Venture

587. In this case, the Defendant GML Host Hospitals knowingly and willfully offered and paid remuneration to the Defendant GML Urologists by way of contracting with GML, a company owned by the Defendant GML Urologists, for the provision of lithotripsy services and made payments for such lithotripsy services that exceeded fair market value for such services and that reflected the volume and/or value of business generated between by the GML Urologists and the GML Host Hospitals.

588. Additionally, the payments made by the GML Host Hospitals to GML were made to induce referrals of other health care business from the GML Urologists to the GML Host Hospitals.

589. The GML Urologists coerced the Defendant GML Host Hospitals into contracting with GML to perform lithotripsy as a mobile service by threatening to take both their federal

healthcare business and their private pay healthcare business elsewhere if the Defendant GML Host Hospitals would not enter into contracts with GML.

590. At the time they were performing lithotripsy at a GLL Host Hospital, Dr. Kamer told Relator that neither he nor his partners Dr. Betrus and Dr. Coury, who all invested in GML, would refer patients to GLL Host Hospitals once they became invested in GML. Instead, they would refer such patients to a GML Host Hospital.

591. At the time he was performing lithotripsy at a GLL Host Hospital, Dr. Davidson who later invested in GML, told Relator that he would no longer refer patients to GLL Host Hospitals once he became invested in GML. Instead, he would refer such patients to a GML Host Hospital.

592. At the time he was performing lithotripsy at a GLL Host Hospital, Dr. Lim, who later invested in GML, told Relator that he would no longer refer patients to GLL Host Hospitals once he became invested in GML. Instead, he would refer such patients to a GML Host Hospital.

593. At the time he was performing lithotripsy at a GLL Host Hospital, Dr. Maatman, who later invested in GML, told Relator that neither he nor his partners Dr. Carothers, and Dr. Schockley would refer patients to GLL Host Hospitals once they became invested in GML. Instead, he would refer such patients to a GML Host Hospital.

594. At the time he was performing lithotripsy at a GLL Host Hospital, Dr. Mertz, who later invested in GML, told Relator that neither he nor his partners, Dr. Kotsis, Dr. Telang, and Dr. Campbell would refer patients to GLL Host Hospitals once they became invested in GML. Instead, he would refer such patients to a GML Host Hospital.

595. At the time he was performing lithotripsy at a GLL Host Hospital, Dr. Salisz, who

later invested in GML, told Relator that he would no longer refer patients to GLL Host Hospitals once he became invested in GML. Instead, he would refer such patients to a GML Host Hospital.

596. At the time he was performing lithotripsy at a GLL Host Hospital, Dr. Stone, who later invested in GML, told Relator that he would no longer refer patients to GLL Host Hospitals once he became invested in GML. Instead, he would refer such patients to a GML Host Hospital.

597. At the time he was performing lithotripsy at a GLL Host Hospital, Dr. Stork, who later invested in GML, told Relator that he would no longer refer patients to GLL Host Hospitals once he became invested in GML. Instead, he would refer such patients to a GML Host Hospital.

598. Relator has knowledge that Dr. Drabik, a GML affiliated Urologist, pressured Cadillac Mercy Hospital into contracting with GML.

599. Relator has knowledge that Dr. Reznicek, a GML affiliated Urologist, pressured Cadillac Mercy Hospital into contracting with GML.

600. Relator has knowledge that Dr. Blix, a GML affiliated Urologist, pressured Bronson and Borgess Hospitals into contracting with GML.

601. Relator has knowledge that Dr. Bour, a GML affiliated Urologist, pressured Bronson and Borgess Hospitals into contracting with GML.

602. Relator has knowledge that Dr. Gauthier, a GML affiliated Urologist, pressured Bronson and Borgess Hospitals into contracting with GML.

603. Relator has knowledge that Dr. Isackson, a GML affiliated Urologist, pressured Bronson and Borgess Hospitals into contracting with GML.

604. Relator has knowledge that Dr. Kronner, a GML affiliated Urologist, pressured Holland and Spectrum Hospitals into contracting with GML.

605. Relator has knowledge that Dr. Lucas, a GML affiliated Urologist, pressured Bronson and Borgess Hospitals into contracting with GML.

606. Relator has knowledge that Dr. Remynse, a GML affiliated Urologist, pressured Battle Creek Health System Hospital into contracting with GML.

607. Relator has knowledge that Dr. Sweeney, a GML affiliated Urologist, pressured Battle Creek Health System Hospital into contracting with GML.

608. Relator has knowledge that Dr. Lonsway, a GML affiliated Urologist, pressured Battle Creek Health System Hospital into contracting with GML.

609. By falsely billing, as set forth in this Complaint, the Defendant GML Host Hospitals knowingly receive payments from the federal government that were kickbacks.

610. Defendant GML receives kickbacks from the Defendant GML Host Hospitals as payments for referral health care business paid by federal health care programs to the Defendant GML Host Hospitals.

611. The Defendant GML Urologists and AKSM share in these kickbacks and participated in actively facilitating the arrangement that provided these kickbacks.

612. The indirect financial relationship between the GML Urologists and the GML Host Hospitals does not qualify for a Stark exception.

613. The GML Urologists cannot make referrals for DHS to a GML Host Hospital.

614. The GML Urologists make such prohibited referrals.

615. The GML Host Hospitals bill for such prohibited referrals.

616. The payments received by the GML Host Hospitals for any inpatient and outpatients services referred by a GML Urologist are illegal under Stark.

Entities Operating in Illinois and Indiana

617. Defendant United Shockwave Therapies has acted as the Syndicator or Management Company for many different UOL Partnerships that operate in Illinois and for many different UOL Partnerships that operate throughout the United States.

618. Defendant United Shockwave Services has acted as the Syndicator or Management Company for many different UOL Partnerships that operate in Illinois and for many different UOL Partnerships that operate throughout the United States.

619. Realtor had discussions with Carol Ann Schleffendorf, an administrator at Westlake Hospital in Chicago, about contracting with UMS.

620. Although such an arrangement would have reduced costs for Westlake Hospital, Ms. Schleffendorf was forced by urologists on staff at Westlake to contract with an UOL Partnership in which they had an ownership interest. These urologists threatened to take urology business elsewhere if Westlake stopped receiving lithotripsy services through the UOL Partnership owned by these urologists. Defendant United Shockwave Therapies controlled this UOL Partnership.

621. Westlake paid $3400 per lithotripsy procedure to the UOL Partnership while receiving $2200 from Medicare as its facility fee for lithotripsy. Westlake was losing money on lithotripsy services provided to Medicare patients.

622. Relator faced a similar situation with Morris Hospital. Morris Hospital inquired about contracting with a UMS controlled UOL Partnership for the rental of lithotripsy services.

UMS would have been able to provide these services at per procedure fees lower than those Morris Hospital was paying to Defendant United Shockwave Therapies.

623. Morris Hospital informed Relator that the Hospital could not contract with a UMS controlled UOL Partnership because Dr. Slutsky would take his patients elsewhere if the Morris Hospital did not use "his" UOL Partnership.

624. At the relevant time, Dr. Slutsky was the only urologist practicing at Morris Hospital. Accordingly, he controlled all of Morris Hospital's business for urological services.

625. Morris Hospital informed Relator that it would not be able to contract with UMS since Dr. Slutsky informed Morris Hospital that he would no longer refer his patients to Morris Hospital if Morris Hospital was no longer under contract to a United Shockwave controlled or managed UOL Partnership for the provision of lithotripsy services.

626. In this case, the Defendant United Shockwave Host Hospitals knowingly and willfully offered and paid remuneration to the Defendant United Shockwave Urologists by way of contracting with a Defendant John Doe United Shockwave UOL Partnership for the provision of lithotripsy services and made payments for such lithotripsy services that exceeded fair market value for such services and that reflected the volume and/or value of business generated between by the United Shockwave Urologists and the United Shockwave Host Hospitals.

627. Additionally, the payments made by the United Shockwave Host Hospitals to a United Shockwave UOL Partnership were made to induce referrals of other health care business from the United Shockwave Urologists to the United Shockwave Host Hospitals.

628. The United Shockwave Urologists coerced the Defendant United Shockwave Host Hospitals into contracting with a United Shockwave UOL Partnership to perform lithotripsy as a mobile service by threatening to take both their federal healthcare business and their private

pay healthcare business elsewhere if the Defendant United Shockwave Urologists would not enter into contracts with a United Shockwave UOL Partnership owned by such Urologists.

629. Relator has knowledge that United Shockwave Services and United Shockwave Therapies caused a loss of lithotripsy business at St. Joseph Regional Medical Center in South Bend, Indiana ("St. Joe's-South Bend").

630. St. Joe's-South Bend had been under contract to a UMS controlled lithotripsy services company that did not have physician ownership.

631. When United Shockwave Therapies entered South Bend with a UOL Partnership, the urologists who invested in this UOL Partnership tried to get St. Joe's-South Bend to change their lithotripsy services contract to their provider.

632. When St. Joe's-South Bend refused to do so, the urologists took their lithotripsy business to their physician-invested site at St. Mary's Hospital.

633. By falsely billing, as set forth in this Complaint, the Defendant United Shockwave Host Hospitals knowingly receive payments from the federal government that were kickbacks.

634. Each Defendant United Shockwave UOL Partnership receives kickbacks from the Defendant United Shockwave Host Hospitals with which it has a contract as payments for referral health care business paid by federal health care programs to such Host Hospitals.

635. The Defendant United Shockwave Urologists and Defendant United Shockwave Services and United Shockwave Therapies share in these kickbacks and participated in actively facilitating the arrangement that provided these kickbacks.

636. The indirect financial relationship between the United Shockwave Urologists and the United Shockwave Host Hospitals does not qualify for a Stark exception.

637. The United Shockwave Urologists cannot make referrals for DHS to a United Shockwave Host Hospital under contract to any UOL Partnership owed by them..

638. The United Shockwave Urologists make such prohibited referrals.

639. The United Shockwave Host Hospitals bill for such prohibited referrals.

640. The payments received by the United Shockwave Host Hospitals for any inpatient and outpatients services referred by a United Shockwave Urologist are illegal under Stark.

641. In this case, Defendant Lincolnland Lithotripsy has acted as the Syndicator or Management Company in John Doe UOL Partnerships operating in Illinois and under contract to John Doe Host Hospitals located in Illinois.

642. Defendant Lincolnland Lithotripsy, the John Doe UOL Partnerships controlled by it, and the John Doe Host Hospitals under contract to such John Doe UOL Partnerships have all participated in a copycat fraudulent scheme pursuant to which each shared in kickbacks.

AKS and Stark Applied to the John Doe Defendants

643. Based on Relator's experiences, there are numerous UOL Partnerships that follow the copycat fraudulent business models described herein.

644. The following defendants act as the Syndicator or Management Company in similar ventures: United Shockwave Therapies, United Shockwave Services, Allied Metro Medical, Lithotripsy Management Associates, and Metropolitan Lithotripter Associates, HealthTronics and Lincolnland Lithotripsy.

645. Other parties who participate in each of these UOL Partnerships is yet unknown except for some of the Syndicators and some of the UOL Partnerships. The John Doe Defendants are all participants in these ventures.